AUTHORITY: Secs. 501, 502, 510, 513, 514, 515, 518, 519, 520, 522, 701, 704, 801, 803 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 352, 360, 360c, 360d, 360e, 360h, 360i, 360j, 360l, 371, 374, 381, 383).

SOURCE: 61 FR 52654, Oct. 7, 1996, unless otherwise noted.

EFFECTIVE DATE NOTE: At 61 FR 52654, Oct. 7, 1996, part 820 was revised, effective June 1, 1997. For the convenience of the user, the superseded text is set forth following the revised text.

Subpart A—General Provisions

§ 820.1 Scope.

(a) *Applicability.* (1) Current good manufacturing practice (CGMP) requirements are set forth in this quality system regulation. The requirements in this part govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use. The requirements in this part are intended to ensure that finished devices will be safe and effective and otherwise in compliance with the Federal Food, Drug, and Cosmetic Act (the act). This part establishes basic requirements applicable to manufacturers of finished medical devices. If a manufacturer engages in only some operations subject to the requirements in this part, and not in others, that manufacturer need only comply with those requirements applicable to the operations in which it is engaged. With respect to class I devices, design controls apply only to those devices listed in § 820.30(a)(2). This regulation does not apply to manufacturers of components or parts of finished devices, but such manufacturers are encouraged to use appropriate provisions of this regulation as guidance. Manufacturers of human blood and blood components are not subject to this part, but are subject to part 606 of this chapter.

(2) The provisions of this part shall be applicable to any finished device as